REMARKS

Remaining Claims

Claims 1 and 14 have been amended to more clearly point out and distinctly claim the invention. Support for the phrase "wherein the step of creating is performed after a contact lens container is sealed by the the laminated film" can be found on page 4, the first complete paragraph (lines 4-11). After these amendments are entered, twenty-One (21) claims (Claims 1 – 16 and 22-26) remain pending in this application through this Amendment.

Amendment objection

Applicants have cancelled the matter introduced in the amendment filed 01/17/2003.

Rejection of Claim under 35 USC §112

Claim 14 has been amended to overcome the Examiner's rejection under 35 USC §112, second paragraph.

Rejection of Claims under 35 USC §103(a)

Claims 1-10, 13 and 15-16 were rejected under 35 USC 103(a) as being unpatentable over Kiyosaki JP 08-047784, in view of Edwards et al. '059. This rejection is respectfully traversed for the following reasons.

Applicants respectfully submit that there is no motivation to combine the primary reference (Kiyosaki JP 08-047784) with secondary references (Edwards et. '059). It is well established that the motivation to modify the prior art must flow from some teachings in the art that suggest the desirability or incentive to make the modification needed to arrive at the claimed invention (See MPEP §2143). The references are to be considered in their entirety (See MPEP §2141.02 on page 2100-120).

Applicants submit herewith the English translation of Kiyosaki JP 08-047784, translated by Tapic International Co., Ltd..

Considered as a whole, Kiyosaki is related to "a marking process for a blister package sheet for <u>imprinting marks</u>, such as a product name and lot number of a product to be packaged, <u>on a container film of a blister package sheet with a laser beam</u>, characterized in that <u>PVC is used</u>

- as the container film and a gas laser beam is used as the laser beam". As stated by Kiyosaki, his invention is based on the discovery "from the results of various experiments of irradiating a laser beam on those materials that irradiate a laser beam to a polypropylene would simply sublimate or evaporate part of the material to form a recessed portion, whereas in case of PVC, not only embossed portion would be formed but also the recessed portion, particularly, the boundary surface of the recessed portion, would be disclored" [0005]. By specifying PVC as the material for a package film in blister wrapping sheet, Kiyosaki aims at simplifying a marking process and reducing cost (Abstract, [0006]). When Kiyosaki stated that "[t]he important point in the invention is the use of PVC as the material for the container film" ([0011]), Kiyosaki provides motivation limited only to laser marking of a PVC container film, of which a blister container is made. Kiyosaki does not disclose nor suggest anything about laser marking of a cover film which is adhered to the container film, anything about laser making of a laminated film having a metal film and a plastic film affixed to the metal film, and anything about laser marking of a laminated film after it seals a contact lens container. Applicants submit that when Kiyosaki is considered in its entirety. there is no teaching in Kiyosaki that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention.

Edwards et al. '059 discloses a laminated film. However, Edwards et al. '059 does not disclose anything about laser making of a laminated film having a metal film and a plastic film affixed to the metal film. What Edwards et ,059 disclosed is thermal transfer priting of a laminated film (col. 4, lines 1-4; col. 7, lines 5-15; col. 9, lines 9-18). Thermal transfer printing has disadvantages, such as those stated by Applicants on page 1, the fourth paragraph (lines 20-26) of the specification:

A <u>thermal transfer printing process</u> for marking blister packs which are subsequently exposed to sterilization is known, for example, from EP-0 646.471. The result of the marking, however, is not particularly satisfying, because it is too full of contrasts and cannot therefore be optimally coordinated with the packaging design. Furthermore, the process entails the consumption of a large quantity of material. Moreover, <u>using present</u> technology, the marking still has to be carried out on rolled material, i.e. on film which is generally wound around a roller, because it is not possible to a mark containers that are already sealed. [Emphasis added]

Furthermore, Edwards et al. '059 teaches that thermal transfer printing of a laminated film is performed before it seals a container (col. 8, line 40 to col. 9, line 10). Edwards et al. '059 does not disclose nor suggest anything about laser marking of a laminated film <u>after it seals a contact lens</u> container.

In addition, when the primary reference and the secondary reference are combined, they do not teach or suggest all the claim limitations, namely, "creating marks on the laminated film by removing said plastic film down to said metal film without perforating the metal film or by changing the plastic film in a manner that a visible color change occurs, by means of a laser, wherein the step of creating is performed after a contact lens container is sealed by the the laminated film". It is well established that the prior art reference (or references when combined must teach or suggest all the claim limitations (See MPEP §2143). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit that the primary reference, alone or in combination with the secondary reference, does not provide any motivation or guidance to a person skilled in the art to make necessary changes to its disclosure to arrive at the present invention; the combination of the cited references not teach or suggest all the claim limitations; and as such a *prima facie* case of obviousness can not be established. Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection.

Claims 1-13 and 15-16 were rejected under 35 USC 103(a) as being unpatentable over Kiyosaki JP 08-047784, in view of Edwards et al. '059 and Roy '771. The rejection over claims 1-13 and 15-16 is respectfully traversed for the following reasons.

The combination of Kiyosaki with Edwards et al. '059 also forms the basis for the rejection of claims 1-13 and 15-16 under 35 USC 103(a) in combination with one additional secondary reference (Roy '771). As discussed above, the combination of Kiyosaki with Edwards et al. '059 **does not** render the present invention as currently claimed obvious. The additional secondary reference (Roy '771) **can not** fill the gap left by the combination of Kiyosaki with Edwards et al. '059. Moreover, the primary reference teaches against use of a solid laser in laser marking of a container film, "because the solid laser, which has a short wavelength of around 1 μ m, passes through the container film and can not heat the container film, whereas the CO₂ laser, which has a wavelength of about 10 μ m, can heat the film" ([0011]). Applicants submit that the Applicants invention as currently claimed is patentable over Kiyosaki JP 08-047784, in view of Edwards et al. '059 and Roy '771. Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection.

Claims 1-16 were rejected under 35 USC 103(a) as being unpatentable over Kiyosaki JP 08-047784, in view of Edwards et al. '059 and Roy '771, further in view of Bornfleth et al. '683. The rejection over claims 1-16 is respectfully traversed for the following reasons.

The combination of Kiyosaki with Edwards et al. '059 and Roy '771 also forms the basis for the rejection of claims 1-16 under 35 USC 103(a) in combination with one additional secondary reference (Bornfleth et al. '683). As discussed above, the combination of Kiyosaki with Edwards et al. '059 and Roy '771 **does not** render the present invention as currently claimed obvious. The additional secondary reference (Bornfleth et al. '683) **can not** fill the gap left by the combination of Kiyosaki with Edwards et al. '059 and Roy '771. Applicant respectfully submits that the present invention as currently claimed is patentable over Kiyosaki in view of Edwards et al. '059 and Roy '771, further in view of Bornfleth et al. '683. Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection.

Claims 1-13, 15-16 and 22-26 were rejected under 35 USC 103(a) as being unpatentable over Kiyosaki JP 08-047784, in view of Edwards et al. '059, Roy '771, and Kim et al. '878. This rejection is respectfully traversed for the following reasons.

The combination of Kiyosaki with Edwards et al. '059 and Roy '771 also forms the basis for the rejection of claims 1-16 under 35 USC 103(a) in combination with one additional secondary reference (Bornfleth et al. '683). As discussed above, the combination of Kiyosaki with Edwards et al. '059 and Roy '771 **does not** render the present invention as currently claimed obvious. The additional secondary reference (Kim et al. '878) **can not** fill the gap left by the combination of Kiyosaki with Edwards et al. '059 and Roy '771. Applicant respectfully submits that the present invention as currently claimed is patentable over Kiyosaki in view of Edwards et al. '059 and Roy '771, further in view of Kim et al. '878. Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection.

CONCLUSION

For the foregoing reasons, Applicants submit that Claims 1-16 and 22-26 are patentable over the cited prior arts. Applicant respectfully requests reconsideration and withdrawal of the claim rejections set-forth in the Office Action and allowance of claims 1-16 and 22-26.

Should the Examiner believe that a discussion with Applicants' representative would further the prosecution of this application, the Examiner is respectfully invited to contact the undersigned. Please address all correspondence to Thomas Hoxie, Novartis Corporation, Corporate Intellectual Property, One Health Plaza, Bldg. 430, East Hanover, NJ 07936-1080. The Commissioner is hereby authorized to charge any other fees which may be required under 37 C.F.R. §§1.16 and 1.17, or credit any overpayment, to Deposit Account No. 19-0134.

Respectfully submitted,

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